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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,023	04/02/2004	Salvatore V. Pizzo	5405-304	2746

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EXAMINER	
LE, EMILY M	
ART UNIT	**PAPER NUMBER**
1648	
MAIL DATE	**DELIVERY MODE**
11/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,023	PIZZO ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14 and 16-20* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-13, 15 and 21-27 are cancelled. Claims 14 and 16-20 are pending. Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/04/2006. Claims 14 and 16-19 are under examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the rejection, Applicant argues that the Office has misapplied the enablement requirement. Applicant specifically notes that the enablement requirement is met if the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. Applicant further argues that Applicant provided a working example demonstrating the induction of a prophylactic immune response, while directing the Office's attention to Figure 6. Applicant additionally argues that Applicant does not have to adequately

guide or direct the use of method of claim 17 for the induction of a prophylactic or protective immune response is well established in the patent literature.

Applicant's arguments have been considered, however, none are persuasive. Contrary to Applicant's assertion, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The factors considered, as noted in the previous office action, in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In the instant case, Applicant does not contain any working example demonstrating that the administration of Compound 48/80 with an antigen **prophylactically prevents bacterial infections, viral infections, fungal infections, parasitic infections and cancer.** It should be noted that the broadest reasonable interpretation of the claimed invention is not limited to the induction of a prophylactic or therapeutic immune response, however, in light of the specification, the interpretation includes the induction of a prophylactic immune response **to prevent bacterial infections, viral infections, fungal infections, parasitic infections and cancer**, which Applicant has not demonstrated. Applicant has not demonstrated that the administration of Compound 48/80 prevents the noted infections and cancer.

Additionally, contrary to Applicants' assertion, Figure 6 of the specification does not demonstrate such either. Figure 6 of the specification is directed at demonstrating the adjuvant activity of Compound 48/80 rather then the ability of Compound 48/80 to prevent infections and cancer. Furthermore, while Applicant's reference and citation of other patent literatures is noted, however, Applicant is reminded that each patent application is treated on its own merits and not that of other patents.

Additionally, as noted in the rejection, the broadest reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host. In view of this interpretation and in light of the disclosure, the claims are also directed at preventing the entry of one microorganism into host cells. In the instant case, Applicant has not demonstrated that the administration of Compound 48/80 prevents the entry of one microorganism into any host cells.

As previously presented, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claimed invention is directed at a method of inducing a prophylactic immune response in a subject with the administration of an immunogen and a mast cell activator, compound 48/80. The claims are not limiting to the type of prophylactic treatment.

Lines 13-15, page 14 of the specification discloses: **the present invention can be used prophylactically to prevent...bacterial infections, viral infections, fungal infections, parasitic infections and cancer.** Hence, in view of this disclosure, the breadth of the claims encompasses prophylactically, prevent, bacterial infections, viral infections, fungal infections, parasitic infections and cancer.

Additionally, the broadest and reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host.

While the specification does contain working examples, however, none of the examples commensurate in scope with the claimed invention. At the very most, the working examples are directed at the induction of a therapeutic immune response with the use of a known immunogen and compound 48/80 as an adjuvant. However, there does not exist any working examples demonstrating or evidencing the induction of a prophylactic immune response. Furthermore, it should be noted that there is no evidence that entry of any microorganism is prevented.

Furthermore, the specification does not contain any guidance or direction directing the use of the claimed method as a prophylactic method. In the instant case, the specification is defective for a method of inducing a prophylactic immune response. Therefore, it is clear from the lack of evidence that the specification is not enabling for the claimed invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Mielcarek et al. is withdrawn in view of Applicant's response.

6. Claims 14 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosok et al.[1] in view of Lenney et al.[2]

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[1] Rosok et al. U.S. Patent No. 4834976, published May 30, 1989.
[2] Lenney et al. Antimicrobial action of Compound 48/80 against protozoa, bacteria and fungi. Journal of Pharmaceutical Sciences. May 1997, Vol. 66, No. 5, 702-705

The claims are directed at the simultaneous administration of an immunogen and compound 48/80 with a pharmaceutical carrier to a subject to induce an immune response. Claim 16, which depends on claim 14, requires that the administration be parenteral. Claim 18, which depends on claim 14, requires the immune response to be therapeutic. Claim 19, which depends on claim 14, requires the immune response to comprise a humoral immune response.

Rosok et al. teaches a composition comprising an immunogen and antimicrobial agent with a pharmaceutical carrier. [Claim 17, columns 28-29, in particular.] Rosok et al. also teaches the administration of the composition to induce a prophylactic and therapeutic immune response. [Claim 22, column 30, in particular.]

Rosok et al. does not specify the use of Compound 48/80 as an antimicrobial agent.

However, at the time the invention was made, Lenney et al. teaches the use of Compound 48/80 as an antimicrobial agent.

Hence, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use compound 48/80 as the antimicrobial agent in the composition of Rosok et al. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so inhibit microbial growth. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the Compound 48/80 is an antimicrobial agent.

Additionally, Rosok et al. teaches that the composition may be administered parenterally. [Lines 57-65, column 8, in particular.] Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to administer the composition parenterally. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so facilitate the administration of the composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because parental administration is routinely practiced in the art.

Conclusion

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily M. Le/
Patent Examiner
Art Unit 1648

/E.Le/